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**EXHIBIT 7**

**RESPONSE TO SMDA OF 1990**

**SUMMARY OF SAFETY AND EFFECTIVENESS DATA**

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**DEVICE NAME:** ***PULPDENT Desensitizer***

**PREDICATE DEVICES:** American Dental Products *Wetting Agent and Desensitizer*  
Health-Dent *Hema-Glu*  
Miles Inc. *Gluma*

**DESCRIPTION AND INTENDED USE:** ***Pulpdent DESENSITIZER*** is a dental desensitizer used to control postoperative and microleakage sensitivity in teeth undergoing treatment or restoration. It can be used under veneers, inlays, crowns, onlays, amalgams and composite resins and to treat cervical or root sensitivity. ***Pulpdent DESENSITIZER*** is a mixture of hydroxyethylmethacrylate and glutaraldehyde in water, which can be applied to all prepared cavities, to dentin and enamel, with or without the smear layer removed. ***Pulpdent DESENSITIZER*** controls dentinal fluid flow by bonding with the proteins in the tubules and thereby producing a physiologic barrier.

**COMPARISON WITH PREDICATE PRODUCTS:** ***Pulpdent DESENSITIZER*** is substantially equivalent in composition and intended use as the predicate products. Please see Exhibit 5 for the entire comparison.

**SAFETY AND EFFECTIVENESS:** According to the NIH Technology Assessment Conference on Effects and Side-Effects of Dental Restorative Materials, "General usage of these materials over about 20 years indicates a high benefit-to-risk ratio... composites... are relatively trouble free. There is no evidence of short or long term risk...there is no suspicion of any problems after literally billions of procedures in the United States." Please see Exhibit 6 for the complete journal articles.